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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,599	01/13/2006	Marie-Christine Secretin	3712036.00702	1833
29157	7590	11/18/2011		
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER BEKKER, KELLY JO	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			11/18/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No. 10/564,599	Applicant(s) SECRETIN, MARIE-CHRISTINE	
	Examiner KELLY BEKKER	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-7 and 11-23 is/are pending in the application.
- 5a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-7, 11-14, 22, 23 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/11</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Amendments made September 20, 2011 have been entered;
Claims 1-7 and 11-23 remain pending;
Claims 15-21 have been withdrawn from consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 103(a) rejection of claims 1-3, 5, 6, 8, 10-14, and 22-25 as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1) has been withdrawn in light of applicant's arguments made September 20, 2011.

The 103(a) rejection of claims 4 and 7 as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997) has been withdrawn in light of applicant's arguments made September 20, 2011.

Claims 1-3, 5, 6, 11-14, and 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1) and Kratky et al (EP 01048226 A1).

Kuslys et al (Kuslys) teaches of an infant formula (page 2 lines 15-16) comprising a source of lipids comprising fish oil (page 6 lines 14-23) which includes the Long Chain Polyunsaturated Fatty Acid (LC-PUFA) comprising docosahexaenoic acid (DHA), a source of carbohydrates (page 6 lines 6-13), a source of sweet whey protein which is modified by the removal of the casino-glyco-macropeptide (CGMP) (page 2 lines 35 and 36) wherein the protein is at about 1.8g/100kcal (page 3 lines 5-9), other beneficial substances (page 7 lines 28-29), water, and salts which when combined with water formed electrolytes, including sodium, calcium, magnesium, chloride, and potassium

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(page 7 lines 12-22 and page 8 lines 1-2). Kuslys teaches that the ratio of whey protein to casein is from 60-70% whey to 30-40% casein, thus teaching that the protein encompasses 60-70% whey protein (page 3 lines 27-32). Page 9 lines 21-25, Kuslys teaches that the whey protein comprises about 33-86% of the total protein (6% whey protein/(6% whey protein +10% non-fat milk solids + 2% alpha lactalbumin rich whey protein source); 50% whey protein/(50% whey protein +8% non-fat milk solids + 0% alpha lactalbumin rich whey protein source)). As hydrolysis is the process of breaking down a molecule and Kuslys teaches that the proteins are not hydrolyzed or treated by any other break down process, one of ordinary skill in the art would expect that the non hydrolyzed proteins as taught by Kuslys are intact as recited in claim 8. Kuslys teaches that in another embodiment, the proteins are hydrolysed. Refer specifically to page 3 lines 21-22.

Kuslys is silent to the proteins as partially hydrolyzed and the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobacteria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG as recited in claim 5, to the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1, and an Na/K ratio of around 0.4mmol as recited in claim 14.

Van Hoey-De-Boer et al (Hoey) teaches that an infant formula with health promoting action is formed with probiotics Bifidobacterium including Bifidobacterium Longum (B. longum) and a Lactobacillus strain including Lactobacillus rhamnosus GG (Lactobacillus paracasei rhamnosus GG) (abstract and paragraphs 0004, 0005, 0014, and 0018). Hoey teaches that the preparation aids in the prevention and treatment of disorders of the gastrointestinal tract (paragraph 0001).

Wilson teaches of a nutritional composition for inclusion in infant formulas (abstract and paragraph 0018). Wilson teaches that infant formulas suitable for use should contain all vitamins and minerals considered to be essential in the daily diet (paragraph 0019). Wilson teaches that a preferred infant formula comprises 460mg of calcium and 333mg of phosphorus and thus a calcium to phosphorus weight ratio of about 1.4 and 160mg of sodium which is about 6.96mmol of sodium and 650mg of

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potassium which is about 16.62mmol of potassium, and thus an Na/K ratio of about 0.4mmol (paragraph 0020).

Kratky et al (Kratky) teaches of an infant formula (abstract) comprising a source of lipids comprising fish oil (paragraph 0024), a source of carbohydrates (paragraph 0023), and a source of sweet whey protein from which the casino-glyco-macropptide (CGMP) has been removed (paragraph 0017) wherein the protein is less than 2g/100kcal, including at about 1.8g/100kcal (paragraph 0028). Kratky teaches that the protein fraction can be hydrolyzed or partially hydrolysed, i.e. less hydrolyzed, in order to prevent allergic reactions in infants and make the protein easier to digest (paragraph 0018).

Regarding the protein as partially hydrolyzed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to partially hydrolyze the protein of the infant formula of Kuslys in order for the protein to be more allergenic friendly and easier to digest as taught by Kratky.

Regarding the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobacteria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the probiotics Bifidobacteria and Lactobacillus paracasei rhamnosus GG in the composition of Kuslys in view of Hoey in order to form an infant formula which aids in the prevention and treatment of disorders of the gastrointestinal tract as taught by Hoey, thus promoting better infantile health.

Regarding the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 and an Na/K ratio of around 0.4mmol, it would have been obvious to one of ordinary skill in the art for the infant formula as taught by Kuslys to comprise a calcium to phosphorus weight ratio of about 1.4 and a Na/K ratio of about 0.4mmol in view of Wilson. One of ordinary skill in the art would have been motivated to use the calcium to phosphorus weight ratio and the Ma/K molar ratio as taught by Wilson, as Wilson teaches that the ratios provide for a preferred infant formula, and as the infant formula composition of Wilson contain all the vitamins and minerals considered to be

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essential to the daily diet and as Kuslys teaches that the infant formula may comprise ingredients so that it is nutritionally complete (page 6 lines 32-35). Furthermore, to include and vary the amount of nutrients would have been obvious and routine determination to one of ordinary skill in the art based on the nutritional effect of the final food product.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1) and Kratky et al (EP 01048226 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997).

Kuslys in view of Hoey teaches of an infant formula comprising probiotic Bifidobacterium longum and Lactobacillus paracasei rhamnosus GG, as discussed above.

Kuslys is silent to the bifidobacteria longum as the BB536 strain as recited in claims 4 and 7.

Holm teaches probiotic foods improve the gut microbiota and through this human health (page 4). Holm teaches that there are a limited number of commercially available probiotics, including Lactobacillus paracasei rhamnosus GG (L. Rhamnosus GG) and Bifidobacterium Longum consisting of BB 536 (B. Longum BB 536) and SBT-2928 (page 14). Holm teaches that the knowledge of health benefits of probiotics is increasing rapidly and that (L. Rhamnosus) was known to assist in the modulation of the immune system and B. longum was known to have anti tumor properties (pages 15-16).

Ishibashi et al (Ishibashi) teaches that the number of bifidobacteria in bottle fed infants is lower than that in breast fed infants (page 150). Ishibashi teaches that infants administered B. longum BB536 has enhanced early colonization of bifidobacteria and formation of bifidobacteria flora, accompanied by reduction of necrotizing enterocolitis and other intestinal tract infections (page 153).

Regarding the bifidobacteria longum as the BB536 strain, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the B. longum as taught by Kuslys in view of Hoey to be either BB536 or SBT-2928 as the strands of probiotics which are commercially available for foods is limited and that is the selection for B. longum as taught by Holms. One would have been further motivated for the B. longum to be BB536 in order to form a product which would enhance the early colonization of bifidobacteria and formation of bifidobacteria flora in the infant and promote a reduction of necrotizing enterocolitis and other intestinal tract infections as taught by Ishibashi.

Claims 1-3, 5, 6, 11-14, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1).

Kratky et al (Kratky) teaches of an infant formula (abstract) comprising a source of lipids comprising fish oil (paragraph 0024) which includes the Long Chain Polyunsaturated Fatty Acid (LC-PUFA) comprising docosahexaenoic acid (DHA), a source of carbohydrates (paragraph 0023), a source of sweet whey protein which is modified by the removal of the casino-glyco-macropeptide (CGMP) (paragraph 0017) wherein the protein is less than 2g/100kcal, including at about 1.8g/100kcal (paragraph 0028), other beneficial substances so that it contains adequate nutrients to sustain healthy human life (paragraphs 0027 and 0032), water, and salts which when combined with water formed electrolytes, including sodium, calcium, magnesium, chloride, and potassium (paragraphs 0030 and 0032). Kratky teaches that the protein comprises about 97-98.5% whey protein (paragraph 0009). Kratky teaches that the protein can be less hydrolyzed, thus teaching that the protein is partially hydrolyzed (paragraph 0018).

Kratky is silent to the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobacteria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG as recited in claim 5, to the formula as comprising a

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calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1, and an Na/K ratio of around 0.4mmol as recited in claim 14.

Van Hoey-De-Boer et al (Hoey) teaches that an infant formula with health promoting action is formed with probiotics Bifidobacterium including Bifidobacterium Longum (B. longum) and a Lactobacillus strain including Lactobacillus rhamnosus GG (Lactobacillus paracasei rhamnosus GG) (abstract and paragraphs 0004, 0005, 0014, and 0018). Hoey teaches that the preparation aids in the prevention and treatment of disorders of the gastrointestinal tract (paragraph 0001).

Wilson teaches of a nutritional composition for inclusion in infant formulas (abstract and paragraph 0018). Wilson teaches that infant formulas suitable for use should contain all vitamins and minerals considered to be essential in the daily diet (paragraph 0019). Wilson teaches that a preferred infant formula comprises 460mg of calcium and 333mg of phosphorus and thus a calcium to phosphorus weight ratio of about 1.4 and 160mg of sodium which is about 6.96mmol of sodium and 650mg of potassium which is about 16.62mmol of potassium, and thus an Na/K ratio of about 0.4mmol (paragraph 0020).

Regarding the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobacteria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the probiotics Bifidobacteria and Lactobacillus paracasei rhamnosus GG in the composition of Kratky in view of Hoey in order to form an infant formula which aids in the prevention and treatment of disorders of the gastrointestinal tract as taught by Hoey, thus promoting better infantile health.

Regarding the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 and an Na/K ratio of around 0.4mmol, it would have been obvious to one of ordinary skill in the art for the infant formula as taught by Kratky to comprise a calcium to phosphorus weight ratio of about 1.4 and a Na/K ratio of about 0.4mmol in view of Wilson. One of ordinary skill in the art would have been motivated to use the calcium to phosphorus weight ratio and the Ma/K molar ratio as taught by Wilson, as

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Wilson teaches that the ratios provide for a preferred infant formula, and as the infant formula composition of Wilson contain all the vitamins and minerals considered to be essential to the daily diet and as Kratky teaches that the infant formula may comprise ingredients so that it is nutritionally complete (paragraphs 0027 and 0030). Furthermore, to include and vary the amount of nutrients would have been obvious and routine determination to one of ordinary skill in the art based on the nutritional effect of the final food product.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997).

Kratky in view of Hoey teaches of an infant formula comprising probiotic Bifidobacterium longum and Lactobacillus paracasei rhamnosus GG, as discussed above.

Kratky is silent to the bifidobacteria longum as the BB536 strain as recited in claims 4 and 7.

Holm teaches probiotic foods improve the gut microbiota and through this human health (page 4). Holm teaches that there are a limited number of commercially available probiotics, including Lactobacillus paracasei rhamnosus GG (L. Rhamnosus GG) and Bifidobacterium Longum consisting of BB 536 (B. Longum BB 536) and SBT-2928 (page 14). Holm teaches that the knowledge of health benefits of probiotics is increasing rapidly and that (L. Rhamnosus) was known to assist in the modulation of the immune system and B. longum was known to have anti tumor properties (pages 15-16).

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Regarding the bifidobacteria longum as the BB536 strain, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the B. longum as taught by Kratky in view of Hoey to be either BB536 or SBT-2928 as the strands of probiotics which are commercially available for foods is limited and that is the selection for B. longum as taught by Holms. One would have been further motivated for the B. longum to be BB536 in order to form a product which would enhance the early colonization of bifidobacteria and formation of bifidobacteria flora in the infant and promote a reduction of necrotizing enterocolitis and other intestinal tract infections as taught by Ishibashi.

Response to Arguments

Applicant's arguments in the remarks filed September 20, 2011 and declaration filed March 4, 2011 have been considered but are not convincing.

Applicant's arguments regarding the prior art rejections have been considered but are not convincing. Applicant argues that hindsight has been utilized and there is no motivation to combine the cited references as the references as the references are directed towards unrelated products with completely different objectives. Applicant's argument is not convincing as it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper; See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971); The references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); In this case, motivation for combining the references has clearly been provided in the rejection; and finally it has been held that a prior art reference must

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either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention; See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); In this case, all the references are directed toward nutritional compositions and inclusion of components within infant formulas, which is within the field of applicant's endeavor.

Applicant argues in the remarks and declaration that there is a synergistic effect from the combination of at least 40% modified sweet whey protein and probiotics which provide for certain unexpected and surprising beneficial effects. Applicant supports this argument with references to the specification and exhibits 1-3. Applicant's argument is not convincing as (1) the evidence compares the conventional formulas to conventional formulas with added probiotics; the evidence is not commensurate in scope with the claims and/or does not compare the closest prior art of record; (2) while the evidence indicates health promoting action when probiotics are added to infant formulas this result does not demonstrate a synergistic effect as there is no correlation or comparison done with the infant formulas at a range of whey protein contents; and thus the evidence does not support applicant's argument; and (3) while the evidence indicates health promoting action when probiotics are added to infant formulas this result does not demonstrate surprising and unexpected effects; probiotics were known to generate bifidobacterium which was known to provide for health benefits, such as shown by Van Hoey-De-Boer and Ishibashi et al (previously cited on the 892 mailed December 14, 2009); and thus the evidence does not support applicant's argument.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kelly Bekker/
Primary Examiner